IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DISTRICT

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	)	
	)	Case No. 08 C 7231
Plaintiffs,	)	
	)	Consolidated for all purposes with Case No. 09-cv-6053
v.	)	
	)	
APOTEX INC., and APOTEX CORP.,	)	Judge Robert M. Dow, Jr.
Defendants.	)	

PLAINTIFF PFIZER'S SUPPLEMENTAL MEMORANDUM
IN SUPPORT OF PFIZER'S MOTION TO DISMISS
DEFENDANT APOTEX'S COUNTERCLAIMS

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Dated: November 12, 2009

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I. INTRODUCTION

Pfizer's Delaware patent infringement suit against Apotex has been transferred to this Court and consolidated with another suit filed by Pfizer in this Court (Case No. 08-7231, the "Illinois Action") against Apotex based on the same Lipitor® ANDA filed by Apotex.[1] After transfer, this Court determined that the Delaware Complaint (D.I. 25 in Case No. 09-6053, the "Delaware Complaint") should govern the consolidated action and Apotex has now filed its Answer and Counterclaims to the Delaware Complaint (D.I. 110).

As it did in response to Pfizer's Illinois Action, Apotex seeks to litigate not only the '995 patent and its reissue (RE667) on which Pfizer originally sued, but also three patents (the '104, '156, and '971 patents or "non-asserted patents") which Pfizer has never asserted against Apotex.

Pursuant to this Court's directions (D.I. 108, 109), Pfizer now moves to dismiss Apotex's counterclaims against the non-asserted patents for the same reasons that it sought dismissal in the original Illinois Action before this Court. (*See* D.I. 54, 56, and 79). Additionally, Pfizer moves to dismiss Apotex's new counterclaim and defenses of non-infringement and invalidity against RE667 because they are inadequately pled. The basis for this motion is the same as that previously presented to this Court in Pfizer's motion to dismiss Apotex's counterclaims and defenses against the '995 patent. (*See* D.I. 56 at pp. 17-18).

As ordered by the Court (D.I. 109), Pfizer supports the instant motion to dismiss by this supplemental memorandum which is limited to factual and legal events subsequent to the original briefing in this Court and by its prior memoranda (D.I. 56 and 79) which are incorporated herein by reference.

[1] Pfizer filed a Petition for Mandamus with the Federal Circuit to review this transfer decision and Apotex's opposition was filed on November 9, 2009. The Federal Circuit has not yet ruled on the Petition.

II. FACTUAL UPDATE

Since Pfizer's original briefing on Apotex's counterclaims in the Illinois Action, Pfizer sued Mylan for infringement of the '156 patent as well as on two other patents not at issue here. *Pfizer Inc. v. Mylan Inc.*, No. 09-cv-441 JJF (D. Del.); *Pfizer Inc. v. Mylan Inc.*, 09-cv-079 IMK (N.D. W. Va.). This Mylan litigation involves a different ANDA filed by Mylan for Lipitor® and presents facts and circumstances not present in the instant dispute with Apotex. Apotex and Mylan are totally different and unrelated generic drug manufacturers.

Additionally, on October 16, 2009, Sandoz (also separate and unrelated to Apotex (and Mylan)) filed counterclaims (as well as a separate complaint) against Pfizer seeking declaratory judgment relief against the non-asserted patents with respect to Sandoz' ANDA for a generic copy of Pfizer's Caduet® product. *Pfizer v. Sandoz*, No. 09-cv-742 JJF (D. Del.); *Pfizer v. Sandoz*, No. 09-cv-2392 CMA MJW (D. Colo.); and *Sandoz v. Pfizer*, No. 09-cv-2457 CMA MJW (D. Colo.). Caduet® contains atorvastatin calcium as one of its active ingredients and the non-asserted patents are part of the several "Lipitor®" patents listed in the FDA's Orange Book for Caduet®. In response, Pfizer moved on November 9th to dismiss Sandoz' declaratory judgment counterclaims (as well as Sandoz' separate declaratory judgment complaint) for lack of a justiciable case or controversy for the same basic reasons that Pfizer has previously presented to this Court in its opening and reply memoranda in support of the instant Motion to Dismiss. Sandoz' answering memorandum is not due until November 30, 2009.

III. LEGAL UPDATE

As discussed in Pfizer's opening and reply memoranda (D.I. 56 and 79), Apotex's decision to wait out the patent term of the '893 patent divests this Court of subject matter

jurisdiction with respect to the non-asserted patents, because those patents have no immediate or substantial impact on Apotex. Recently, the District Court for the District of New Jersey was presented with a similar situation and concluded that the ANDA applicant failed to establish the real and immediate injury necessary to establish declaratory judgment jurisdiction. *See Teva Pharmaceuticals USA, Inc. v. Eisai Co., Ltd.*, No. 08-2344, 2009 WL 2905534, at *11-13 (D. N.J. Sept. 9, 2009) [attached hereto as Exhibit A].

In *Teva*, Ranbaxy was the first ANDA filer and therefore had a 180 day-exclusivity period to market generic donepezil (sold under the brand name Aricept®). *Teva*, 2009 WL 2905534, at *3. Ranbaxy had filed a Paragraph IV certification against four Eisai patents protecting donepezil ("the DJ patents"). Ranbaxy, however, filed a Paragraph III certification against U.S. Patent No. 4,895,841 ("the '841 patent"), which meant that Ranbaxy could not launch its generic product until after the '841 patent expired in November 2010. *Id.* Eisai elected not to bring a suit against Ranbaxy. *Id.* Ranbaxy's Paragraph IV certification and Eisai's failure to litigate gave Ranbaxy the 180-day exclusivity period for the DJ patents.

Teva sought to break Ranbaxy's 180-day exclusivity by challenging not only the '841 patent via a Paragraph IV certification in its ANDA, but also the four other Eisai patents protecting donepezil ("the DJ patents") by a separate declaratory judgment action against Eisai.[2] *Id.* Eisai had not asserted the DJ patents against Teva, and in fact disclaimed two of the patents and also granted Teva covenants not to sue on the other two patents. *Teva*, 2009 WL 2905534, at *5. Ultimately Eisai moved to dismiss Teva's declaratory judgment counterclaims on the DJ patents pursuant to Fed. R. Civ. P. 12(b)(1). *Id.* at *6.

[2] Gate Pharmaceuticals ("Gate"), which the Court found to be a division of Teva, also filed an ANDA for generic donepezil. *Teva*, 2009 WL 2905534, at *3. The actions of Gate do not appear to be relevant to the instant Motion to Dismiss.

Initially, the Court noted that there appeared to be no adverse legal interests between Teva and Eisai due to the covenants not to sue. *Id.* at *7. However, Teva asserted a different injury due to the four DJ patents: FDA-approval-blocking injury. *Id.* Under the Hatch-Waxman Act, both Ranbaxy and Teva had shared 180-day exclusivity periods for the marketing of generic donepezil. *Id.* Ranbaxy obtained its exclusivity period due to its first-filed Paragraph IV certification against the DJ patents and Teva received its exclusivity due to its Paragraph IV certification against the '841 patent. *Id.*

In a separate, but related, patent suit, Eisai sued Teva for infringement of the '841 patent due to Teva's ANDA filing. *Teva*, 2009 WL 2905534, at *4. The *Eisai v. Teva* patent suit created a 30-month stay of the FDA's approval of Teva's ANDA. *Id.* The 30-month stay expired while the *Eisai v. Teva* patent suit was still ongoing which caused the Court to grant a preliminary injunction to prevent Teva from marketing any generic donepezil while the *Eisai v. Teva* case remained pending. *Id.* The *Teva* Court found that the preliminary injunction resulted in Teva being precluded from marketing any generic donepezil product until at least November 2010, the expiration date of the '841 patent. *Id.*

Regarding Eisai's motion to dismiss Teva's declaratory judgment claims based on the four DJ patents, the *Teva* Court found that the "dormant" 180-day exclusivity period that Teva sought to break was not the only barrier to market entry. *Teva*, 2009 WL 2905534, at *11. Rather, the preliminary injunction issued against Teva also prevented Teva from marketing any generic product until the expiration date of the '841 patent. *Id.*

In a finding important to the instant Motion to Dismiss, the *Teva* Court found that the preliminary injunction "has the same effect on Teva as Ranbaxy's Paragraph III certification does on Ranbaxy... ." *Id.* at *12. The preliminary injunction caused the *Teva* Court to find that

"the potential injury alleged by Teva lacked the sufficient immediacy and reality required to establish declaratory judgment jurisdiction." *Id.* The *Teva* Court noted that Teva was required to show that declaratory judgment jurisdiction existed at the time of filing and at all stages of the review. *Id.* (citations omitted). "Even if this Court could possibly exercise jurisdiction in the future," the Court commented, "jurisdiction is wanting at this time." *Id.* Thus, the *Teva* Court concluded that due to the preliminary injunction, which had the same effect as a Paragraph III certification against the '841 patent, there was no justiciable Article III controversy "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* (citing *Medimmune, Inc. v. Genetech, Inc.*, 549 U.S. 118, 127 (2007)). Further, the *Teva* Court noted that even if the jurisdictional requirements of *Medimmune* were met, the Court would exercise its discretion under the Declaratory Judgment Act, 28 U.S.C. § 2201, to decline jurisdiction. *Teva*, 2009 WL 2905534, at *13. The Court determined that it was appropriate to decline jurisdiction to conserve judicial resources. *Id.*

The *Teva* case is relevant to Pfizer's Motion to Dismiss because it illustrates how Apotex's Paragraph III certification against the '893 patent eliminates the necessary immediate and real harm to Apotex required to establish declaratory judgment jurisdiction. The *Teva* case turned on a preliminary injunction, but the Court equated the injunction to a Paragraph III certification as both have the same ultimate effect of preventing Teva from marketing its generic donepezil product during the patent term of the '841 patent. Here, Apotex has agreed to wait out the full patent term of the '893 patent, thus, pursuant to *Teva*, there can be no declaratory judgment jurisdiction because there is no real and immediate harm to Apotex now. Whether there may be such a harm in the future, after the '893 patent expires, is not relevant. Apotex must show that it is harmed now.

IV. CONCLUSION

For all the above reasons, the Court should dismiss Apotex's Counterclaims regarding the Unasserted Patents.

RESPECTFULLY SUBMITTED,

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Dated: November 12, 2009

CERTIFICATE OF SERVICE

I, Jeffrey M. Drake, caused to be served a copy of the foregoing:

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by filing same with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the following counsel of record:

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